Claims

What is claimed is:

1. A composition comprising first and second nucleic acid sequences, wherein said first nucleic acid sequence is a truncated A subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, and said second nucleic acid sequence is a truncated B subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, with the proviso that each of said truncated subunit coding regions has a 5' deletion and encodes a subunit peptide not having an amino terminal bacterial signal peptide.

2. The composition of claim 1, wherein said first and second nucleic acid sequences are present in a single nucleic acid construct.

3. The composition of claim 2, wherein said nucleic acid construct is a plasmid vector.

4. The composition of claim 2, wherein the first and second nucleic acid sequences are operably linked to a transcriptional control element.

5. The composition of claim 4, wherein said transcriptional control element is a heterologous promoter.

6. The composition of claim 1 wherein said first and second nucleic acid sequences are present in separate nucleic acid constructs.

7. The composition of claim 6, wherein said separate nucleic acid constructs are plasmid vectors.

8. The composition of claim 1, wherein the truncated subunit coding regions are obtained or derived from the same bacterial ADP-ribosylating exotoxin.

9. The composition of claim 8, wherein said bacterial ADP-ribosylating exotoxin is a cholera toxin (CT).

10. The composition of claim 8, wherein said bacterial ADP-ribosylating exotoxin is an *E. coli* heat labile enterotoxin (LT).

11. The composition of claim 1, wherein at least one of the truncated subunit coding regions has been genetically modified to detoxify the subunit peptide encoded thereby.

12. The composition of claim 11, wherein the truncated A subunit coding region has been genetically modified to disrupt or inactivate ADP-ribosyl transferase activity in the subunit peptide encoded thereby.

13. The composition of claim 1, wherein the truncated A subunit coding region has been further genetically modified so as to delete a C-terminal KDEL or RDEL motif in the subunit peptide encoded thereby.

14. The composition of claim 1 further comprising an antigen of interest.

15. The composition of claim 14, wherein said antigen is from a bacterial, viral or parasitic pathogen.

16. The composition of claim 1, further comprising a third nucleic acid sequence that encodes an antigen of interest.

17. The composition of claim 16, wherein said antigen is from a bacterial, viral or parasitic pathogen.

18. The composition of claim 16, wherein said third nucleic acid sequence is present in a nucleic acid construct that does not contain said first or said second nucleic acid sequence.

19. The composition of claim 18, wherein the nucleic acid construct containing the third nucleic acid sequence is a plasmid vector.

20. The composition of claim 16, wherein said third nucleic acid sequence is present in a nucleic acid construct that also contains at least one of said first or said second nucleic acid sequence.

21. The composition of claim 20, wherein the nucleic acid construct containing the third nucleic acid sequence is a plasmid vector.

22. The composition of claim 1, wherein said composition is in a particulate form.

23. The composition of claim 22, wherein said particulate composition is suitable for transdermal delivery via a particle delivery device.

24. The composition of claim 1, further comprising a pharmaceutically acceptable vehicle or excipient.

25. The composition of claim 1, wherein the first and second nucleic acid sequences are coated onto a core carrier particle.

26. The composition of claim 25, wherein the core carrier particle has an average diameter of about 0.1 to about 10μm.

27. The composition of claim 25, wherein the core carrier particle comprises a metal.

28. The composition of claim 27 wherein the metal is gold.

29. The composition of claim 28 wherein the core carrier particle has a diameter of about 1 to about 3 μm.

30. The composition of claim 1 further comprising a transfection facilitating agent.

31. The composition of claim 30, wherein the transfection facilitating agent is a liposome.

32. A composition comprising first and second nucleic acid sequences, wherein said first nucleic acid sequence is a modified A subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, and said second nucleic acid sequence is a B subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, with the proviso that said modified A subunit coding region and said B subunit coding region each encode a mature subunit peptide, and with the further proviso that the modified A subunit coding region has been genetically modified so as to delete a C-terminal KDEL or RDEL motif in the subunit peptide encoded thereby.

33. The composition of claim 32, wherein said first and second nucleic acid sequences are present in a single nucleic acid construct.

34. The composition of claim 33, wherein said nucleic acid construct is a plasmid vector.

35. The composition of claim 33, wherein the first and second nucleic acid sequences are operably linked to a transcriptional control element.

36. The composition of claim 35, wherein said transcriptional control element is a heterologous promoter.

37. The composition of claim 32, wherein said first and second nucleic acid sequences are present in separate nucleic acid constructs.

38. The composition of claim 37, wherein said separate nucleic acid constructs are plasmid vectors.

39. The composition of claim 32, wherein the B and modified A subunit coding regions are obtained or derived from the same bacterial ADP-ribosylating exotoxin.

40. The composition of claim 39, wherein said bacterial ADP-ribosylating exotoxin is a cholera toxin (CT).

41. The composition of claim 39, wherein said bacterial ADP-ribosylating exotoxin is an *E. coli* heat labile enterotoxin (LT).

42. The composition of claim 32, wherein at least one of the B or modified A subunit coding regions has been genetically modified to detoxify the subunit peptide encoded thereby.

43. The composition of claim 42, wherein the modified A subunit coding region has been genetically modified to disrupt or inactivate ADP-ribosyl transferase activity in the subunit peptide encoded thereby.

44. The composition of claim 32, wherein the modified A subunit coding region and the B subunit coding region have each been truncated by a 5' deletion whereby each of said truncated subunit coding regions encodes a subunit peptide not having an amino terminal bacterial signal peptide.

45. The composition of claim 32 further comprising an antigen of interest.

46. The composition of claim 45, wherein said antigen is from a bacterial, viral or parasitic pathogen.

47. The composition of claim 32 further comprising a third nucleic acid sequence that encodes an antigen of interest.

48. The composition of claim 47, wherein said antigen is from a bacterial, viral or parasitic pathogen.

49. The composition of claim 47, wherein said third nucleic acid sequence is present in a nucleic acid construct that does not contain said first or said second nucleic acid sequence.

50. The composition of claim 49, wherein the nucleic acid construct containing the third nucleic acid sequence is a plasmid vector.

51. The composition of claim 47, wherein said third nucleic acid sequence is present in a nucleic acid construct that also contains at least one of said first or said second nucleic acid sequence.

52. The composition of claim 51, wherein the nucleic acid construct containing the third nucleic acid sequence is a plasmid vector.

53. The composition of claim 32, wherein said composition is in a particulate form.

54. The composition of claim 53, wherein said particulate composition is suitable for transdermal delivery via a particle delivery device.

55. The composition of claim 32 further comprising a pharmaceutically acceptable vehicle or excipient.

56. A composition according to claim 55, wherein the first and second nucleic acid sequences are coated onto a core carrier particle.

57. The composition of claim 56, wherein the core carrier particle has an average diameter of about 0.1 to about 10μm.

58. The composition of claim 56, wherein the core carrier particle comprises a metal.

59. The composition of claim 58, wherein the metal is gold.

60. The composition of claim 59 wherein the core carrier particle has a diameter of about 1 to about 3 μm.

61. The composition of claim 32 further comprising a transfection facilitating agent.

62. The composition of claim 61, wherein the transfection facilitating agent is a liposome.

63. A method for enhancing an immune response against an antigen of interest in a vertebrate subject, the method comprising:

(a) administering the antigen of interest to the subject;

(b) providing an adjuvant composition comprising first and second nucleic acid sequences, wherein said first nucleic acid sequence is a truncated A subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, and said second nucleic acid sequence is a truncated B subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, with the proviso that each of said truncated subunit coding regions has a 5' deletion and encodes a subunit peptide not having an amino terminal bacterial signal peptide; and

(c) administering said adjuvant composition to the subject, whereby upon introduction to the subject, the first and second nucleic acid sequences are expressed to provide subunit peptides in an amount sufficient to elicit said enhanced immune response against the antigen of interest.

64. The method of claim 63, wherein the antigen of interest and the adjuvant composition are administered to the same site in the subject.

65. The method of claim 63, wherein the antigen of interest and the adjuvant composition are administered concurrently.

66. The method of claim 65, wherein the antigen of interest and the adjuvant composition are combined to provide a single vaccine composition.

67. The method of claim 63, wherein the antigen of interest is from a bacterial, viral or parasitic pathogen.

68. The method of claim 67, wherein step (a) entails administering a third nucleic acid sequence that encodes said antigen of interest.

69. The method of claim 63, wherein the adjuvant composition is administered to the subject in particulate form.

70. The method of claim 69, wherein said first and second nucleic acid sequences are coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.

71. The method of claim 63, wherein the subject is a mammal.

72. A method for enhancing an immune response against an antigen of interest in a vertebrate subject, the method comprising:

(a) administering the antigen of interest to the subject;

(b) providing an adjuvant composition comprising first and second nucleic acid sequences, wherein said first nucleic acid sequence is a modified A subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, and said second nucleic acid sequence is a B subunit coding region obtained or derived from a bacterial ADP-ribosylating exotoxin, with the proviso that said modified A subunit coding region and said B subunit coding region each encode a mature subunit peptide, and with the further proviso that the modified A subunit coding region has been genetically modified so as to delete a C-terminal KDEL or RDEL motif in the subunit peptide encoded thereby; and

(c) administering said adjuvant composition to the subject, whereby upon introduction to the subject, the first and second nucleic acid sequences are expressed to provide subunit peptides in an amount sufficient to elicit said enhanced immune response against the antigen of interest.

73. The method of claim 72, wherein the antigen of interest and the adjuvant composition are administered to the same site in the subject.

74. The method of claim 72, wherein the antigen of interest and the adjuvant composition are administered concurrently.

75. The method of claim 74, wherein the antigen of interest and the adjuvant composition are combined to provide a single vaccine composition.

76. The method of claim 72, wherein the antigen of interest is from a bacterial, viral or parasitic pathogen.

77. The method of claim 76, wherein step (a) entails administering a third nucleic acid sequence that encodes said antigen of interest.

78. The method of claim 72, wherein the adjuvant composition is administered to the subject in particulate form.

79. The method of claim 78, wherein said first and second nucleic acid sequences are coated onto a core carrier particle and administered to the subject using a particle-mediated delivery technique.

80. The method of 72, wherein the subject is a mammal.